JUL 2 2 2011

VIII. 510(k) Summary

A. Sponsor/Submitter:	Marine Polymer Technologies, Inc. 107 Water Street Danvers, MA 01923 Phone: 781-270-3200 Fax: 781-270-1133
B. Contact Person	Sergio Finkielsztein President Phone: 781-270-3200
C. Date of Submission:	June 1, 2011
D. Trade (Brand) Name:	MP 719
E. Common Name:	Bone Hemostasis Implant Material
F. Classification Number/ Name:	"Bone Wax"
G. Regulatory Class:	Unclassified
H. Product Code:	MTJ

I. Predicate Devices:

Marine Polymer Technologies, Inc.- Taliderm (K070557)
Ceremed, Inc. Ostene CT Soluble Bone Hemostasis Implant Material (K091636)
Orthocon, Inc. HemaSorb™ Resorbable Hemostatic Bone Putty (K063330)
United States Surgical Corporation Bone Wax – (K971680)

J. Intended Use:

MP 719 is indicated for use as an implant material and for use in the control of bleeding from bone surfaces. The material may be used during surgical procedures and in treating traumatic injuries.

K. Device Description:

MP 719 is a sterile, resorbable, non-woven membrane material comprised of shortened fibers of poly-N-acetyl glucosamine, isolated from microalgae, intended for use in the management of bleeding.

MP 719 is available in a range of sizes from 4cm x 4cm to 10cm x 10cm.

L. Summary of Substantial Equivalence:

Summary of Safety and Effectiveness Data Table

	TEST	DESCRIPTION	STUDY	CONCLUSION
BENCH TOP	Chemical Analysis	Chemical/Physical tests	IR identification, elemental analysis, ash, absence of protein, % moisture	pass according to specifications
	Safety	Safety tests	bioburden, endotoxin	pass according to specifications
	Shelf Life	Stability	3 year real time Stability Study	pass according to specifications
	Device Hardness	Mechanical	Hardness Testing of MP719	MP719 and Bone Wax exhibit similar mechanical properties
	Handling Properties	Bench top	Hardness Testing of MP719	MP719 and Bone Wax handle similarly in bench top experiments.
		in vivo	Evaluation of Hemostasis produced by MP719 Implanted in Cortical Defects in the Rabbit Femur	MP719 and Bone Wax handle similarly in *in vivo* experiments.
ANIMAL STUDIES	Biocompatibility	Cytotoxicity	L929 MEM Elution Test	No biological reactivity (Grade 0)
		Sensitization	Kligman Maximization Test	0% sensitization
		Irritation	Intracutaneous Injection Test	Negligible irritant
			USP Class VI - Intracutaneous Injection in rabbits	no signs of erythema or edema
		Genotoxicity	Samonella typhimurium REVERSE MUTATION ASSAY	non-mutagenic
			Mammilian Genotoxicity Publication	non-mutagenic
		Implantation	USP Class VI - Intramuscular Implantation in Rabbits	no inflamation, encapsulation, hemmorrhage, necrosis or discoloration
			Intramuscular Implantation Test- ISO, 2 week	non-reactive
			Intramuscular Implantation Test- ISO, 4 week	non-reactive
			Intramuscular Implantation Test- ISO, 12 week	non-reactive
		Hemocompatibility	ASTM Hemolysis Testing on MP719	both test article and test article extract are non-hemolytic
		Systemic Toxicity	USP Class VI -Systemic Injection in Mice	no significantly greater biological reactivity than control
Comparison of MP 719 and legally marketed bone wax	Implantation	Bone Implant	Implantation Study of MP719 in Femur Cortical Bone of Rabbit	Both MP719 and Bone Wax lacked any macroscopically detectable adverse reactions.
	Hemostasis	Comparative Hemostasis	Evaluation of Hemostasis produced by MP719 Implanted in Cortical Defects in the Rabbit Femur	MP719 and Bone Wax were considered equivalent in their ability to bring about hemostasis.

Marine Polymer Technologies has submitted information on indication for use, biocompatibility and performance characteristics to establish that MP 719 is substantially equivalent to currently marketed predicate devices. MP 719 has essentially the same intended use as the predicate devices. Results of scientific testing have ensured that the material is biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use. Non-clinical testing was conducted. Animal testing was performed to simulate clinical conditions with no adverse effects noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Marine Polymer Technologies, Inc.
% Mr. Sergio Finklesztein
President
107 Water Street
Danvers, Massachusetts 01923

JUL 22 2011

Re: K111524
Trade/Device Name: MP 719
Regulatory Class: Unclassified
Product Code: MTJ
Dated: June 28, 2011
Received: June 29, 2011

Dear Mr. Finklesztein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

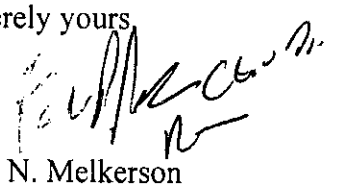
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 2:

Indications for Use Statement

INDICATIONS FOR USE

510(k) Number K111524

Device Name MP 719

INDICATIONS:

MP719 is indicated for use as an implant material and for use in the control of bleeding from bone surfaces. The material may be used during surgical procedures and in treating traumatic injuries.

MP719 is intended for use under the direction of a healthcare professional.

Prescription Use X (Per 21 C.F.R. 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Kanne for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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